

REMARKS

Upon entry of the present amendment, claims 1 and 12 will have been amended while claims 11 and 18 will have been canceled without prejudice or disclaimer.

In view of the hereincontained amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of each of the outstanding rejections set forth in the above-mentioned Official Action. Such action is respectfully requested and is now believed to be appropriate and proper.

In the outstanding Official Action, the Examiner objected to claims 11 and 18 under 37 C.F.R. § 1.75(c) as being of improper dependent form. The Examiner asserted that these claims are redundant in view of the amendment to independent claims 1 and 12.

By the present response, Applicant has canceled these claims, thus rendering the Examiner's objection thereto moot.

In the outstanding Official Action, the Examiner rejected claims 1-3, 5-9 and 11-20 under 35 U.S.C. § 103(a) as being unpatentable over OUCHI (U.S. Published Application No. 2002/0123667) in view of RYDELL (U.S. Patent No. 5,035,696) and further in view of the teachings of the WEAVER et al. (U.S. Patent No. 5,536,248). The Examiner further rejected claims 1-3, 5-7 and 11-20 under 35 U.S.C. § 103 as being unpatentable over SLATER (U.S. Patent 5,482,054) in view of RYDELL and further in view of the teachings of WEAVER et al.

Claims 8 and 9 were rejected under 35 U.S.C. § 103 as unpatentable over SLATER, RYDELL and WEAVER as applied in further view of the teachings of SUTTON et al. (U.S. Patent No. 5,762,613).

Applicant respectfully traverses each of the above-noted rejections and submit that they are inappropriate, particularly with regard to the combination of features recited in the claims as herein amended. Accordingly, Applicant respectfully requests reconsideration of the outstanding rejections and an indication of the allowability of all the claims pending herein, in due course.

In setting forth the rejection, the Examiner admits that each of the primary references (SLATER et al. and OUCHI) discloses two conductive wires within a single guide channel wherein each of the wires is provided with an insulative coating. The Examiner relies upon RYDELL to teach wires that can be individually insulated or alternatively that the wires may be uninsulated and may be provided with two channels for individually housing the wires. Thus, the Examiner concludes that it would be obvious to provide the OUCHI or the SLATER et al. flexible tube with two channels for receiving the individual conductive wires and obviating the need for insulative coatings on the individual wires. The Examiner additionally relies on WEAVER for a teaching of providing the two channels as circular lumens to "more fittingly receive the leads".

As noted above, Applicant respectfully traverses each of the above rejections. In responding to Applicant's arguments, the Examiner agrees with Applicant's prior characterization of the WEAVER reference but maintains that RYDELL clearly teaches endoscopic bipolar devices may provide insulated wires in a single lumen or may provide uninsulated wires in separate lumens or channels.

Applicant respectfully submits that the Examiner has impermissibly expanded the teachings of RYDELL beyond their intended scope. In this regard, Applicant notes that the conductive wire 26 of RYDELL cannot contain insulation to perform its intended use.

In this regard, in both embodiments of RYDELL (i.e., the embodiment with insulated wires and the embodiment with uninsulated wires), the operative portion of the electrode 26 must remain free of insulation in order to perform its intended function. In other words, and as set forth in the previous remarks, the wire 26 is exposed and cannot have insulation provided therein in order to operate properly. In direct contrast, in both OUCHI and SLATER et al., the conductive wires are merely attached to the operational portions of the respective devices. There is no reason to make the connecting wire of bare uninsulated conductive material.

In direct contrast, there is a logical reason for removing the wire from the extended conductors of RYDELL since the insulation must in any regard be removed from the operative portion of the conductor 26 in order that it may perform its intended function. Thus, because of the difference in function and structure of the RYDELL device as compared to each of the SLATER et al. and OUCHI devices, the teachings of RYDELL are not transferable to the endoscopic tools of SLATER et al. and OUCHI in spite of the fact that all three devices deal with, as the Examiner characterized them, "endoscopic bipolar devices".

In the outstanding Official Action (in the Examiner's Response to Arguments), the Examiner asserts that it is not true that the wires of RYDELL cannot have insulation. However, in proper context, Applicant asserted, in the prior remarks, that since the wire 26 is exposed, as it must be in order to perform its intended function, it cannot have insulation material provided thereon. Of course, other portions of the wire can have insulation as shown in the first embodiment of RYDELL. However, the fact remains that the operative portion of RYDELL consists of an exposed (i.e., uninsulated) conductive

wire. Therefore, it is logical to similarly provide the remainder of the wires to be exposed without insulation thereon.

However, in direct contrast, each of the OUCHI and SLATER et al. devices does not use, as their operative component, a bare conductive wire. Rather, in each of OUCHI and SLATER et al., the ends of the wires are merely connected to jaws 18 or 110 and 112. Thus, there is no reason to make the entire wire without insulation. In other words, the teachings of RYDELL do not translate and transfer to the structure of SLATER et al. and OUCHI.

Further along the same lines, Applicant notes that the RYDELL device is directed to a catheter based device that can be passed through an endoscope into the duodenum to the site of the papilla of Vater and which can be deployed to cut the sphincter of Oddi to allow passage of gallstones from the common bile duct into the duodenum. While RYDELL is, of course as the Examiner points out, a bipolar electrosurgical device, nevertheless, its specialized function is what renders it obvious to utilize exposed (i.e., uninsulated) conductive wires therein. On the other hand, the structures of SLATER et al. and OUCHI do not share the need for an exposed conductive wire operational portion and, thus, have no need for having the conductive wires provided in an uninsulated condition. Thus, contrary to the Examiner's assertions, there is no proper motivation for combining the teachings of RYDELL with those of SLATER et al. or OUCHI.

The Examiner asserts that WEAVER supports the assertion that any shape lumen can be used in a catheter device as an obvious design consideration to one of ordinary skill in the art. Applicant further respectfully traverses this assertion. Initially,

Applicant notes that an assertion of obvious design consideration is not the proper evidentiary standard necessary to support a rejection under 35 U.S.C. § 103. Rather, "obvious design consideration" is a conclusion based upon evidence of obviousness, which the Examiner has not provided.

Nevertheless, Applicant notes that WEAVER does disclose a flexible electrosurgical tool and further discloses circular lumens. However, the lumens of WEAVER are structurally and functionally different than those recited in Applicant's claims as well as structurally and functionally different than those of SLATER et al., and OUCHI, as combined by the Examiner with the teachings of RYDELL. While WEAVER et al. might well disclose at, column 10 lines 28-38, the use of different shaped lumens, at column 15, starting at line 46, WEAVER et al. discloses the structure and uses to which these lumens are put. In particular, WEAVER et al. discloses that the lumens have a minimum wall thickness of 0.005 inches and that one lumen will accommodate a 0.018 mm wire guide while the second lumen is reserved for infusion of contrast medium and a third lumen is reserved for additional instruments such as are later enumerated. However, none of these devices that are disclosed by WEAVER et al. relate to the type of treatment tools that are utilized by SLATER et al. or OUCHI or even by RYDELL. Yet additionally, based on the minimum wall thickness disclosed by WEAVER et al. of 0.005 inches, such wall thickness would not be effective in providing the appropriate insulation necessary for the naked (or bare) wires in the Examiner's proposed combination. Thus, it is respectfully submitted that WEAVER et al. cannot provide the teaching for which the Examiner relies thereupon. In the absence of such a teaching, it is respectfully submitted that the Examiner's rejection, which is based on a

conclusion of design choice that is lacking in evidentiary support, is inappropriate and should be reconsidered and withdrawn.

In order to more clearly emphasize the distinction between the combination of SLATER or OUCHI in view of RYDELL and the teachings of WEAVER, Applicant has further amended the independent claims to define the guide channels as being spaced apart from each other by about 0.5 mm. This spacing is adequate to provide the required electrical insulation which would be necessary in view of the other recited structure of Applicant's claims. Applicant notes that the recited spacing of the guide channels is approximately four times the recited thickness of WEAVER and support for this feature is found at least at paragraph [0031] of the specification. It is provided in order to insulate the bare conductive wires from each other.

This represents yet another explicitly recited feature of Applicant's invention that is not disclosed by any of the references relied upon by the Examiner. Accordingly, for each of the above reasons, and certainly for all of the above reasons, it is respectfully submitted that Applicant's claims are clearly patentable over the combinations of references relied upon by the Examiner. An action to such effect is respectfully requested, in due course.

Applicant's claims 8 and 9 are submitted to be patentable over the cited references based on their own recitations as well as based upon the recitations of the independent claim from which they depend. Moreover, the Examiner has asserted absolutely no motivation to modify the combination of OUCHI or SLATER et al. and RYDELL and WEAVER with the additional teachings of SUTTON et al. The Examiner has merely concluded that such modification would be obvious. This is inappropriate

under 35 U.S.C. § 103. Accordingly, claims 8 and 9 are yet additionally submitted to be patentable over the combination of references relied upon by the Examiner.

Applicant notes that the status of the present application is after final rejection and that once a final rejection has issued, an Applicant does not have a right to amend an application. Nevertheless, in the present situation, Applicant respectfully submits that entry of the present amendment is appropriate and proper and in full compliance with 37 C.F.R. § 1.116. In this regard, Applicant notes that he is merely clarifying a previously expressed feature of Applicant's invention to more clearly emphasize the distinctions between the Examiner's combination and the present invention. Accordingly, Applicant respectfully submits that the present amendment raises no issues requiring further consideration or search and thus should be entered by the Examiner.

SUMMARY AND CONCLUSION

Applicant has made a sincere effort to place the present application in condition for allowance and believes that he has now done so. Applicant has amended the claims to more clearly emphasize the distinction between the present invention and the disclosures of the references relied upon by the Examiner. Applicant has additionally canceled several dependent claims.

Applicant has discussed the references relied upon by the Examiner and has pointed out the shortcomings thereof with respect to the features of Applicant's invention. Applicant has also discussed the recitations of the claims and noted the shortcomings of the combination of references asserted by the Examiner thereagainst. Applicant has additionally pointed out the lack of obviousness and motivation for the proposed combination. Accordingly, Applicant has provided a clear evidentiary basis supporting the patentability of all the claims in the present application and respectfully requests an indication to such effect, in due course.

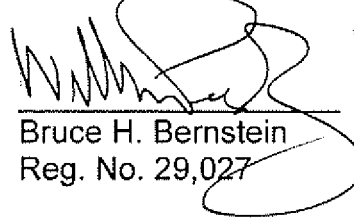
Any amendments to the claims which have been made in this amendment, and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Should an extension of time be necessary to maintain the pendency of this application, including any extensions of time required to place the application in condition for allowance by an Examiner's Amendment, the Commissioner is hereby authorized to charge any additional fee to Deposit Account No. 19-0089.

P23565.A09

Should the Examiner have any questions or comments regarding this Response, or the present application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
Satoshi KIDOOKA

A handwritten signature in black ink, appearing to read 'Bruce H. Bernstein', is written over a horizontal line. The signature is stylized with a large, looping 'B' and 'S'.

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